

Attorney Docket No.: DEX-0314  
Inventors: Salceda et al.  
Serial No.: 10/074,511  
Filing Date: February 12, 2002  
Page 10

#### REMARKS

Claims 1-5, 7 and 8 are pending in the instant application. Claims 1-5 and 7-8 have been rejected. Claim 1 has been amended. New claims 18 and 19 which depend from claim 1 have been added. Support for these amendments is provided in the specification at page 12, lines 29-30 and claim 1. No new matter is added by this amendment. Support for the amendment to the specification may be found in U.S. Provisional Application Serial No. 60/268,289, to which priority is claimed, at page 22, line 1 through page 23, line 24. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. New Matter

The Examiner suggests that the amendment of the claims to read "differential expression in breast cancer" is new matter. The Examiner has acknowledged the instant specification to disclose BSNAs showing a high degree of tissue specificity for the tissue of interest and the mRNA over-expression in matching sample tested to be indicative of SEQ ID NO:65 being a diagnostic marker for cancer. However, the Examiner suggests

Attorney Docket No.: DEX-0314  
Inventors: Salceda et al.  
Serial No.: 10/074,511  
Filing Date: February 12, 2002  
Page 11

that the recitation of the more limited limitation of "breast cancer" is new matter.

Thus, without conceding to correctness of the Examiner's position and in an earnest effort to advance the prosecution of this case, Applicants have replaced the phrase "breast cancer" with --cancer--.

Withdrawal of this rejection is therefore respectfully requested.

**II. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. 101 and 112, first paragraph**

The Examiner has maintained the rejection of claims 1-5, 7 and 8 under 35 U.S.C. 101 and 112, first paragraph because the Examiner suggests that the claimed invention lacks patentable utility due to its not being supported by a specific, substantial and credible utility or, in the alternative, a well-established utility.

Applicants respectfully traverse this rejection.

At the outset, in response to the Examiner's suggestion that SEQ ID NO:65 is not found in Example 1, Applicants respectfully direct the Examiner to page 117, line 12 wherein

Attorney Docket No.: DRX-0314  
Inventors: Salceda et al.  
Serial No.: 10/074,511  
Filing Date: February 12, 2002  
Page 12

"DEX0308\_65 flex DEX0166\_38 DEX308-110" is included in a list of BSGs (defined at page 6 line 9 as a breast specific gene) which were identified in accordance with teachings at page 115, line 30 by mRNA subtraction analysis. As taught at page 116, line 2-3, "DEX0308\_1, DEX0308\_2 corresponds to SEQ ID NO:1, 2, etc." Thus, teachings at page 117, line 12 concerning "DEX0308\_65" correspond to SEQ ID NO:65. It is respectfully requested that the Examiner review these specific sections as they clearly verify that SEQ ID NO:65 is a breast specific gene identified by mRNA subtraction analysis in Example 1.

To further clarify, Applicants have amended the specification to include the Example from page 22-23 of U.S. Provisional Patent Application Serial No. 60/268,289, the teachings of which are stated at page 1, lines 4-6 to be incorporated by reference in their entirety. This Example entitled Suppression subtractive hybridization (Clontech PCR-SELECT) provides evidence that SEQ ID NO:65 (which as taught at page 117, line 12 of the instant application is related to the parent sequence DEX0166\_38 or SEQ ID NO:38 of Provisional Patent

Attorney Docket No.: DEX-0314  
Inventors: Salceda et al.  
Serial No.: 10/074,511  
Filing Date: February 12, 2002  
Page 13

Application Serial No. 60/268,289) is a cancer specific, and more specifically a breast cancer specific gene.

Subtraction experiments such as performed in the instant application are well-accepted methodologies by those skilled in the art. It is understood by those of skill in the art that subtraction experiments by design identify nucleic acids differentially expressed between normal tissue and diseased tissue. The identified nucleic acid sequences are consequently useful as a diagnostic marker for detecting cancer tissue versus normal tissue.

Therefore, the identification of SEQ ID NO:65 by suppression subtractive hybridization is demonstrative of SEQ ID NO:65 being a diagnostic cancer marker. Thus, the specification clearly provides both specific and substantial utility support for the invention as now claimed.

Further, Applicants respectfully disagree with the Examiner's suggestion that the statement in Example 2 that "BSNAs show a high degree of tissue specificity for the tissue of interest" is not supportive of differential expression of SEQ ID NO:65 in breast cancer samples. As discussed in Section I,

Attorney Docket No.: DEX-0314  
Inventors: Salceda et al.  
Serial No.: 10/074,511  
Filing Date: February 12, 2002  
Page 14

supra, SEQ ID NO:65 was identified by Suppression subtractive hybridization and is differentially expressed in breast cancer tissue compared to normal tissue. Thus, the teachings of Example 1 have been shown to provide both specific and substantial utility support for the invention as now claimed. Therefore the Examiner's remarks regarding Example 2 are extraneous in light of the teachings of Example 1.

In conclusion, these experiments demonstrate the credibility of the specific and substantial utility of the instant claimed invention.

Withdrawal of the rejections under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, for lack of utility is therefore respectfully requested.

**III. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. 112, first paragraph**

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the

Attorney Docket No.: DEX-0314  
Inventors: Salceda et al.  
Serial No.: 10/074,511  
Filing Date: February 12, 2002  
Page 15

claimed invention. In particular, the Examiner suggests that the instant specification does not disclose sequences which hybridize with SEQ ID NO:65 and sequences having a degree of identity to the sequence of SEQ ID NO:65 and thus does not specifically provide support that Applicant was in possession of the sequences as being claimed.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 by deleting parts (c) and (d) drawn to hybridizing sequences and sequences with 95% identity with respect to SEQ ID NO:65. Claim 1 as amended is drawn to (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 110, (b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 65, or, (c) an allelic variant of (a) or (b). Allelic variant is defined at page 12, lines 29-32 of the instant specification as two or more alternative naturally occurring forms of a gene, wherein each gene possesses a unique nucleotide sequence. The presence of naturally-occurring allelic variants is well-established. Those skilled in the art could routinely identify such naturally occurring

Attorney Docket No.: DEX-0314  
Inventors: Salceda et al.  
Serial No.: 10/074,511  
Filing Date: February 12, 2002  
Page 16

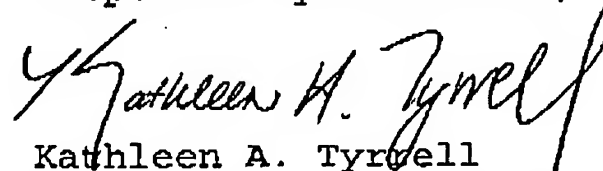
allelic variants of SEQ ID NO:65. Thus, the instant specification places the public in possession of all sequences as claimed, thereby meeting the written description requirements of 35 U.S.C. 112, first paragraph.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph is therefore respectfully requested.

#### IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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